IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRVINIA
AT CHARLESTON

IN RE: AVAULTA PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION **MDL No. 2187**

JANICE PAVEGLIO and JAMES PAVEGLIO,

Plaintiffs,

v.

C. R. BARD, INC., COVIDIEN INC., COVIDIEN PLC, COVIDIEN INTERNATIONAL FINANCE, SA, COVIDIEN TREVOUX, SCS, MAREANE, SA, FLOREANE MEDICAL IMPLANTS SA, SOFRADIM PRODUCTION SAS, JOHNSON & JOHNSON, ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, and GYNECARE,

Defendants.

CIVIL ACTION 2:12-0137

COMPLAINT

COME NOW JANICE PAVEGLIO and JAMES PAVEGLIO as Plaintiffs herein and hereby file this Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs are citizens of the State of Tennessee.

2. Defendant C. R. Bard, Inc. ("Bard") is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Bard as described herein were done

by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3. Defendant Covidien Inc. ("Covidien Inc.") is a Delaware Corporation with its principal place of business in Massachusetts. All acts and omissions of Covidien Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. Defendant Covidien plc ("Covidien plc"), an Irish public limited company with its principal place of business in Massachusetts. All acts and omissions of Covidien plc as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

5. Defendant Covidien International Finance, SA ("CIFSA") is a Luxembourg company with its principal place of business in Luxembourg. All acts and omissions of CIFSA as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

6. Defendant Covidien Trevoux, SCS ("Covidien Trevoux") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Covidien Trevoux as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

7. Defendant Mareane, SA ("Mareane") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Mareane as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

8. Defendant Floreane Medical Implants SA ("Floreane") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Floreane as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

9. Defendant Sofradim Production SAS ("Sofradim") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Sofradim as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

10. Defendant, Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

11. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

12. Defendant, Ethicon Women's Health and Urology is a division of Ethicon, Inc. located in Somerville, New Jersey.

13. Defendant, Gynecare is a division of Ethicon, Inc. located in Somerville, New Jersey.

14. Defendants, when referenced collectively, shall hereinafter referred to as "Defendants".

15. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

16. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

17. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c). Venue is also proper based on the PreTrial Order #1, filed on October 21, 2010, within In Re: Avaulta Pelvic Support Systems Product Liability Litigation (MDL Docket No. 2187) which resides within this District.

FACTUAL BACKGROUND

Stress-Urinary Incontinence and Pelvic Organ Prolapse

18. Defendants promote their medical devices as devices intended to treat stress urinary incontinence and/or pelvic organ prolapse.

19. Stress urinary incontinence ("SUI") is the involuntary loss of urine during movement that puts pressure on the bladder, such as laughing, coughing, or sneezing, or during aerobic or strenuous exercise. Although incontinence is suffered by men and women, it is more common in women and can be caused by menopause or by physical changes that occur to the body during pregnancy or childbirth.

20. Childbirth, for example, can injure the pelvic floor muscles and ligaments that help support a woman's bladder. If these structures weaken, the bladder can move downward, pushing slightly out of the bottom of the pelvis toward the vagina. The movement of the bladder, or other pelvic organs, such as the urethra, cervix or rectum, is known as pelvic organ prolapse ("POP"). A prolapsed bladder can prevent the muscles that ordinarily force the urethra shut from squeezing as tightly as they should, resulting in an involuntary loss of urine.

21. Stress urinary incontinence can be embarrassing and uncomfortable. Pelvic organ prolapse is also uncomfortable and can interfere with urinary and defecatory functions, many daily activities, and sex.

22. Both SUI and POP are, in most cases, treatable. A woman who elects to have her SUI or POP surgically treated has several options. SUI, for example, can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials such as suprapubic mid-urethral "slings" placed under the urethra to provide support Similarly, POP can be corrected through traditional procedures via abdominal or transvaginal surgery. POP can also be surgically addressed using biologic, composite, or synthetic materials.

23. The surgical mesh products manufactured by Defendants are considered Class II medical devices.

24. Under the 510(k) process, a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a "predicate device." A predicate device is one that the FDA has placed into one of three classification categories and "cleared" for marketing.

25. Unlike Class III medical devices, such as an artificial heart or an Automated External Defibrillator, Class II devices do not require "approval" by the FDA. Whereas Class III devices cannot be sold until the manufacturer demonstrates to the FDA, through adequate and well-controlled clinical trials, that the proposed device is safe and effective, there is no such requirement for Class II devices. The "premarket notification" process -- for Class II devices – is not focused on whether the device is safe and effective, but rather is concerned with whether

the proposed device is substantially equivalent to an existing predicate device that was already cleared for marketing by the FDA.

26. Defendants were aware, or should have been aware, of the dangers inherent in its transvaginal mesh products generally, notwithstanding the fact that these products were "cleared" for sale by the FDA.

Background on Covidien Entities

27. Floreane, Sofradim and Covidien Inc. designed and manufactured the Avaulta Anterior and Posterior BioSynthetic Support Systems (used for POP); the Pelvisoft Acellular Collagen BioMesh (used for POP); Pelvicol Acellular Collagen Matrix (used for POP); Pelvilace Biourethral Support System (used for SUI); and Uretex Urethral Support System (used for SUI), including the Products that were implanted in Plaintiff.

28. Floreane, Sofradim and Covidien Inc. have admitted *in judicio* that they are the designers and manufacturers of these Products.

29. Bard marketed, packaged, labeled, sold and distributed these Products in the United States, including the Products that were implanted in Plaintiff.

30. Sofradim is, and at all times relevant was, a subsidiary of Floreane. Floreane is the sole shareholder of Sofradim. Floreane owns 100% of the capital of Sofradim. Floreane controls 100% of the voting rights of Sofradim. Floreane appoints the officers and directors of Sofradim. Floreane has the power to remove the officers and directors of Sofradim.

31. Floreane and Sofradim share the same principal place of business, 116 Avenue Du Formans, Trevoux, France 01600.

32. Sofradim is a "production line" of Floreane.

33. Floreane and Sofradim are members of a tax consolidation group, or "intégration fiscale," organized under French law, whereunder their corporate income taxes are calculated on the basis of their aggregated profits and losses, rather than individually. Floreane is the "head" of this tax group, and files a consolidated tax return for the group and pays taxes on behalf of the group.

34. Floreane is liable for any acts and/or omissions by or through Sofradim. Sofradim is so organized and controlled and its business conducted in such manner as to make it merely an alter ego or business conduit of Floreane. Because Sofradim's assets and capital are subject to the ownership and control of Floreane, Sofradim is undercapitalized and the failure to disregard Sofradim's corporate form would result in the inequitable and unjust result that Plaintiffs may be unable to satisfy any judgment ultimately obtained against Sofradim. Sofradim acts as agent for Floreane. Floreane and Sofradim combine their property and labor in a joint undertaking for profit, with rights of mutual control.

35. Covidien Trevoux and Mareane are direct shareholders of Floreane.

36. Covidien Inc., Covidien Trevoux, Mareane, Floreane and Sofradim are subsidiaries of Covidien plc and are wholly-owned by CIFSA.

37. Covidien plc is a holding company, the purpose of which is to co-ordinate the administration, finances and activities of its subsidiary companies, including Covidien Inc., Sofradim and Floreane, and to act as managers and to direct or coordinate the management of its subsidiary companies or of the business, property and estates of any subsidiary company, including Covidien Inc., Sofradim and Floreane.

38. The Articles of Association of Covidien plc provide in part that it shall indemnify any person who is serving or has served at the request of Covidien plc as a director or executive

officer of another company, joint venture, trust or other enterprise, including a subsidiary of Covidien plc, against any expenses, including attorney's fees, judgments, fines, and amounts paid in settlement actually and reasonably incurred by him or her in connection with any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, to which he or she was, is, or is, threatened to be made a party, or is otherwise involved.

39. CIFSA is a holding company established by Covidien plc to own the operating subsidiaries of Covidien plc, to issue notes, and to perform treasury operations for Covidien plc.

40. When Covidien plc's immediate predecessor, Covidien Ltd., purchased Floreane, Covidien Ltd. acquired Floreane's assets and also assumed Floreane's liabilities. Covidien plc assumed Floreane's liabilities when it merged with and into Covidien Ltd.

41. The financial accounts of Covidien Trevoux, Mareane, Floreane and Sofradim are consolidated within those of CIFSA.

42. Covidien Trevoux, Mareane, Floreane, Sofradim, are part of "Le Comite d/enterprise de l'Unite Economique et Sociale," ("UES") an economic and social unit, organized under French law, which is defined as the "co-existence of an economic and social unity."

43. Covidien Trevoux, Mareane, Floreane, and Sofradim all share the same principal place of business, 116 Avenue Du Formans, Trevoux, France 01600.

44. Covidien Trevoux, Mareane, Floreane and Sofradim are parties to a cash pooling agreement, or "convention de trésorerie," the proceeds of which are ultimately distributed to Covidien plc and/or CIFSA.

45. Covidien plc, CIFSA, Covidien Trevoux, Mareane, Floreane and Sofradim share common officers and directors. Michel Therin is President of both Mareane and Floreane,

"Directeur Général Délégué" for Sofradim, as well as "Vice President of Soft Tissue Repair and Biosurgery for Covidien plc. CIFSA's Managing Director (Principal Executive, Financial and Accounting Officer), Michelangelo Stefani, is the non-partner manager for Covidien Trevoux and a member of the Board of Directors of Floreane.

46. CIFSA conducts no independent business of its own, and its income is derived entirely from the continuing operations and cash flow through distributions from its subsidiaries, including Floreane and Sofradim.

47. CIFSA and/or Covidien plc own any and all trademarks and registered marks associated with Covidien Trevoux, Mareane, Floreane and Sofradim.

48. Covidien plc, CIFSA, Covidien Trevoux and Mareane are liable for any acts and/or omissions by or through Sofradim or Floreane. Floreane and Sofradim are so organized and controlled and their business conducted in such manner as to make them merely alter egos or business conduits of Covidien plc, CIFSA, Covidien Trevoux and Mareane. Because Sofradim's and Floreane's assets and capital are subject to the ownership and control of Covidien plc, CIFSA, Covidien Trevoux and Mareane, Sofradim and Floreane are undercapitalized and the failure to disregard Sofradim's and Floreane's corporate form would result in the inequitable and unjust result that Plaintiffs may be unable to satisfy any judgment ultimately obtained against Sofradim and/or Floreane. Floreane and Sofradim act as agents for Covidien plc, CIFSA, Covidien Trevoux and Mareane. Floreane and Sofradim combine their property and labor with that of Covidien plc, CIFSA, Covidien Trevoux and Mareane in a joint undertaking for profit, with rights of mutual control.

Plaintiff's Medical History and Experience

49. Plaintiff Janice Paveglio was implanted with the Avaulta® Support System and the Gynecare Prolift® ("Products") during surgery performed in the State of Tennessee.

50. The Products were implanted in Plaintiff to treat her pelvic organ prolapse and stress urinary incontinence, the use for which the Products were designed, marketed and sold.

51. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and has endured impaired physical relations with her husband, Plaintiff James Paveglio.

52. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of her injuries including but not limited to the defective design and/or manufacturing of the products implanted inside of her until recently.

Factual Allegations Common to All Counts

53. Defendants' pelvic mesh products incorporate a monofilament polypropylene mesh intended for the treatment of pelvic organ prolapsed and/or stress urinary incontinence. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Moreover, the mesh migrates within the surrounding tissues causing irreparable damage to the tissue including nerve endings residing

within the tissues. Damaged nerve endings do not regenerate and lead to debilitating neuromas suffered by patients such as Plaintiff.

54. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse or stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

55. The Defendants have marketed and sold its pelvic mesh products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products.

56. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Medical Devices have high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making it defective under the law. The Defendants have consistently underreported and withheld information about the propensity of its pelvic mesh products to fail and cause injury and complications, and has misrepresented

the efficacy and safety of its products and, through various means and media, actively and intentionally been misleading the FDA, the medical community, patients, and the public at large.

57. Defendants have known and continue to know that some of the predicate products for their Medical Devices had high failure and complication rates, resulting in the recall of some of these predicate devices; that there were and are differences between the Defendants' Medical Devices and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Medical Devices and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Medical Devices were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continues to mislead the public, including the medical community, health care providers and patients, into believing that the Medical Devices and the procedures for the implantation were and are safe and effective, leading to the prescription for and implantation of the Medical Devices into Plaintiff.

58. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Medical Devices.

59. Defendants failed to design and establish a safe, effective procedure for removal of their pelvic mesh products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Medical Device.

60. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Medical Devices.

61. The Medical Device(s) were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedure for implanting the device, and trained the implanting physicians.

62. The Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Medical Devices, and thus increased the sales of the Medical Devices, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

63. The Medical Device(s) implanted into Plaintiff were in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

64. Plaintiff and her physicians foreseeably used and implanted Defendants' Medical Device(s), and did not misuse, or alter the Medical Device(s) in an unforeseeable manner.

65. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' pelvic mesh products, include without limitation: mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, the recurrent prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other

medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

66. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' pelvic mesh products, have examined each of these injuries, conditions, and complications and determined that they are, in fact, casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

67. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public at large that the pelvic mesh products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

68. These representations were made by Defendants with the intent of inducing Plaintiff, the medical community, and the public to recommend, prescribe, dispense, and purchase the Medical Device for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

69. Defendants acted unreasonably in failing to undertake its duties to properly know the qualities of their products and in representations to Plaintiff and/or to Plaintiff's healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Medical Device was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with the Medical Device was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Medical Device was not adequately tested and were known by Defendants;

d. That the limited clinical testing revealed the Medical Device had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendats failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in its pelvic mesh products, including the pelvic mesh systems, in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g. That the pelvic mesh systems were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h. That patients frequently would need revisionary surgery due to changes in the structure of the Medical Device that would cause it to be become loose, or shift position within the body.

i. That patients needed to be monitored more regularly than usual while using the Medical Device and that in the event the product needed to be removed that the procedure to remove them had a very high failure rate and/or needed to be performed repeatedly.

70. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of the Medical Device, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

71. Defendants had sole access to material facts concerning the defective nature of the Medical Device and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Medical Device.

72. Defendants' concealment and omissions of material facts concerning the safety of its pelvic mesh products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Medical Device; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Medical Device.

73. At the time these representations were made by Defendants, and at the time Plaintiff used the Medical Device, she was unaware of the falsehood of these representations, and reasonably believed them to be true.

74. Defendants knew and had reason to know that the Medical Device could and would cause severe and grievous personal injury to their users, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

75. In reliance upon these false representations, Plaintiff was induced to, and did, use the Medical Device thereby sustaining severe and permanent personal injuries and damages.

76. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Medical Device, as described in detail herein.

77. As a result of Defendants' research and testing or lack thereof, it distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians that the Medical Device was safe for use as a means of providing relief

from stress urinary incontinence and/or prolapse and was as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

78. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiffs' healthcare providers, and the FDA.

79. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Medical Device.

80. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Medical Device specifically that it did not have dangerous and/or serious adverse health safety concerns, and that it was as safe as other means of treating stress urinary incontinence and/or prolapse.

81. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate, including erosion, the difficulty of removing the Medical Device, and the risk of permanent injury.

82. Defendants chose to over-promote the safety, efficacy and benefits of the Medical Device instead.

83. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the

medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Medical Device; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Medical Device.

84. Defendants made claims and representations in documents it submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Medical Device did not present serious health risks.

85. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

86. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals, and other members of the healthcare community, and were made in order to induce Plaintiff, and her healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Medical Device and her healthcare professionals to dispense, recommend, or prescribe the Medical Device.

87. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Medical Device to the public at large, for the purpose of influencing the sales of product known to be dangerous and defective, and/or not as safe as other alternatives.

88. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Medical Device.

89. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use

of the Medical Device. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

90. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Defendants' Medical Device(s), she would not have purchased, used, or relied on Defendants' Medical Device.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

91. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

92. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

93. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

94. As a direct and proximate result of Defendants' negligence, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

95. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

96. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law with respect to their design.

97. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

98. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY - MANUFACTURING DEFECT

99. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

100. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law with respect to their manufacture.

101. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

102. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

103. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

104. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law due to their lack of appropriate and necessary warnings.

105. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

106. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

107. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

108. Defendants made assurances to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purpose.

109. Plaintiff and/or her health care providers chose the Products based upon Defendants' warranties and representations regarding the safety and fitness of the Products.

110. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable and reasonably fit for their intended purpose.

111. Defendants breached these express warranties because the Products implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants had represented.

112. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

113. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

114. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

115. Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purpose for which they were intended.

116. When the Products were implanted in Plaintiff to treat her pelvic organ prolapse and stress urinary incontinence, they were being used for the ordinary purposes for which they were intended.

117. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Products implanted in her.

118. Defendants breached these implied warranties of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for the intended uses as warranted.

119. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Products in Plaintiff body, placing her health and safety in jeopardy.

120. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT VII: LOSS OF CONSORTIUM

121. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

122. As a direct and proximate result of the above-described injuries sustained by Plaintiff Janice Paveglio, her husband, Plaintiff James Paveglio has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

COUNT VIII: PUNITIVE DAMAGES

123. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

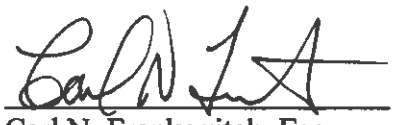
124. Defendants knew or should have known that the Products were defective and presented unreasonable risks of harm to Plaintiff.

125. Defendants' conduct as described in this Complaint, for which Plaintiffs are entitled to recover compensatory damages, manifested a conscious indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Products, including Plaintiff, justifying the imposition of punitive damages.

WHEREFORE, Plaintiffs demand a trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, and any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

DATED: January 20, 2012

By: 

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